CONDITIONS OF LIABILITY INSURANCE FOR CLINICAL TRIALS AND/OR HEALTHY VOLUNTEER STUDIES

I. DEFINITIONS

Insured
The Institution or company sponsoring or performing the Clinical Trials, whose name is indicated in the Policy and in the Certificate of Insurance.

If the Insured named in the Policy and in the Certificate of Insurance only sponsors such trial, but the said trial is performed by other medical institution(s), for the purpose of this insurance the employees of the institution(s): investigator and his/her assistant medical staff, consultants and persons providing medical services, performing and controlling the said trial, shall be deemed to be co-insureds if medical institution(s) is named in the Policy and in the Certificate of Insurance.

Trial Subject
An individual patient or non-patient volunteer who after signing the Informed Consent participates in the clinical trial.

Clinical Research
Any study conducted on a human subject for the purpose of:
a) establishing or demonstrating the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products;
b) identifying side effects of one or more medicinal products; or
c) studying the absorption, distribution, metabolism and excretion of one or more medicinal products
to demonstrate the safety and/or efficacy of such medicinal product.

Clinical Trial
Clinical research that meets one of the following criteria:
a) the inclusion of the Test Subject in a given therapeutic strategy is based on a prior decision that is not in line with standard clinical practice in the Member State concerned;
b) the decision to prescribe investigational medicinal product is taken at the same time as the inclusion of the Test Subject in the clinical trial, or
c) Test Subjects are subject to additional diagnostic or monitoring procedures in addition to standard clinical practice.

Clinical trial with minor intervention
A Clinical Trial that meets all of the following criteria:
a) investigational medicinal products, with the exception of placebos, have a marketing authorisation,
b) according to the clinical trial plan
   ba) the use of investigational medicinal products in accordance with the terms of the marketing authorisation in the Member State concerned, or
   bb) the use of the investigational medicinal product is evidence-based and supported by published scientific evidence of safety and efficacy in any of the Member States concerned,
c) any additional diagnostic or monitoring procedures pose minimal additional risk or burden to the safety of the Test Subjects compared to standard clinical practice in the Member State concerned.

Non-interventional research
Clinical research other than the Clinical Trial

Investigational medicinal product
A medicine that is being tested as part of a Clinical Trial or used as a reference material, such as a placebo.

Standard clinical practice
The usual method of treatment for the treatment, prevention or diagnosis of a disease or condition

Advanced therapeutic investigational medicinal product
Such investigational medicinal product which is an advanced therapeutic investigational medicinal product within the meaning of Article 2(1)(a) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council

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Complementary medicine
A medicine used for the needs of a Clinical Trial as defined in the protocol and used as a non-investigational medicinal product in that trial.

Medical device:
Any instrument, apparatus, appliance, device, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, on human beings for one or more of the following specific medical purposes:
a) diagnose, prevent, monitor, predict, prognosticate, treat or palliate disease;
b) diagnose, monitor, treat, mitigate or compensate for an injury or disability;
c) testing, replacing or modifying anatomy or a physiological or pathological process or condition;
d) providing information by in vitro testing of samples from the human body, including organ, blood and tissue donations;
and which does not achieve its primary intended effect in the human body or human organism by pharmacological or immunological means or by metabolic pathways, but which may be assisted in its action by the mechanisms of action mentioned above.

The following products are also considered medical devices:
a) devices intended to control or promote conception,
b) products intended for cleaning, disinfecting or sterilising the following equipment:
   ba) contact lenses or other articles intended to be placed in or on the eye;
   (bb) products intended to be introduced wholly or partly into the human body by invasive surgical means for the purpose of modifying the anatomy or fixation of parts of the human body, with the exception of products intended for tattooing and body jewellery,
   (bc) substances, combinations of substances or articles intended to fill facial or other skin tissue or mucous membranes by subcutaneous or intradermal injection or submucosal injection or other means of introduction, other than products intended for tattooing.
   bd) equipment intended for use in the reduction, removal or destruction of adipose tissue, such as equipment for liposuction, lipolysis or surgical fat removal;
   be) equipment emitting high-intensity electromagnetic radiation (e.g. infrared, visible light and ultraviolet) intended for use on the human body, including monochromatic and broad-spectrum, coherent and incoherent sources such as lasers and intense flashlight equipment used for skin resurfacing, tattoo or hair removal or other skin treatments;
   bf) devices for brain stimulation which use electric currents or magnetic or electromagnetic fields to penetrate the skull in order to modify neural activity in the brain;
   bg) any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for the diagnosis, prevention, monitoring, forecast, prognosis, treatment or mitigation of disease in humans.

Medical device accessories
An article which is not a medical device in itself but which is intended by its manufacturer to be used in combination with one or more medical devices to enable the medical device(s) to be used as intended or to facilitate in a specific and direct manner the medical use of the medical device(s) for its intended purpose

In vitro diagnostic medical device
Any medical device, whether as a reagent, reagent derivative, calibration and control material, diagnostic kit, apparatus, equipment, machine, software or system, used alone or in combination with other devices, intended by the manufacturer for use in the in vitro testing of samples from the human body, including blood and tissue donation, solely or principally for the purpose of providing information on or for any of the following:
a) a physiological or pathological process or condition;
b) congenital physical or mental impairments;
c) a predisposition to a particular medical condition or disease;
d) to assess the safety and compatibility of potential recipients;
e) to predict the response to a treatment or the reactions it elicits;
f) to determine or monitor therapeutic measures.
Containers for holding samples are considered in vitro diagnostic medical devices.

Container for samples
A vacuum or non-vacuum device specially designed by the manufacturer to receive samples from the human body immediately after collection and to store them for in vitro diagnostic testing

In vitro diagnostic medical device accessory
An article which is not an in vitro diagnostic medical device per se, but which is intended by its manufacturer to be used in combination with one or more specific in vitro diagnostic medical device(s) to enable the in vitro diagnostic medical device(s) to be used as intended or to facilitate in a specified and direct manner the medical use of the in vitro diagnostic medical device(s) in relation to its intended purpose

Clinical trial is hereinafter referred to as Clinical Trial using medicinal products for human use, medical devices and in vitro diagnostic medical devices.

II. INSURED EVENT

1. Insured Event is the death of or any impairment to the health of the Test Subject directly caused by the medication, medical device or in vitro diagnostic medical device used during the Clinical Trial performed or sponsored by the Insured as indicated in the schedule or by the professional actions of the Insured in connection with the insured Clinical Trial.

2. Upon occurrence of the Insured Event determined under Pt. 1 above and in connection with thereof the Insurer will provide coverage **to the Test Subject**

   (i) for such damages for which the Insured is liable for compensation under the Hungarian law in force at the time of the occurrence of the insured event, and/or,
   (ii) for the violation of privacy rights caused to the Test Subjects, as a result of which the Insured is liable to pay restitution under the rules of Hungarian civil law.

3. The Insurer shall cover the costs of legal representation of the Insured, if such costs have been incurred with the prior approval of the Insurer.

4. In accordance with paragraph 2 above, the insurance cover also extends to direct losses suffered by persons other than the Test Subjects as a result of the insured event referred to in paragraph 1 above. The Insurer does not provide cover for restitution out of any violation of privacy rights caused to persons other than the Test Subject.

III. TERRITORIAL AND TIME SCOPE OF INSURANCE

1. This insurance shall cover insured events caused within the territorial scope defined in the insurance policy.

2. This insurace is concluded for the period of the Clinical Trial named in the policy.

3. The insurance cover is upright as of the effective date of the contract. Unless agreed to the contrary the insurance contract comes into effect on the day when the Policyholder paid the first premium (premium instalment) due, as specified in the contract.

4. Claims occurring during the period of insurance or after its termination but not later than within five years following the conclusion of the Clinical Trial shall be covered under this insurance. In case of doubt it shall be assumed that the insured event occurred on the date of the first medical examination concluded in respect of the injury out of participation in the Clinical Trial.

IV. EVENTS AND LOSSES NOT COVERED BY THIS INSURANCE

For the purpose of these terms under claim and compensation also the violation of personal rights and the restitution based on such are to be understood. This insurance shall not cover the following:

1. any claims arising from circumstance(s) or occurrence(s) which has been notified under any Policy or Certificate of Insurance attaching prior to the inception of this Policy;

2. claims on the account of injuries inflicted on purpose;

3. claims arising from the fact that the investigational medicinal product did not meet the expectations or did not produce the expected beneficial results;

4. injuries, the occurrence of which is highly probable owing to the nature of the conducted clinical trial, or which do not exceed the acceptable degree according to the present state of medical knowledge;

5. claims arising out of addiction caused by investigational medicinal product if such possibility was known;

6. injuries, which would have occurred even in the case of not participating in the clinical trials;

7. in the cases when the study includes the trial (testing) of a investigational medical product, no indemnification is paid to the Trial Subject who did not receive such a medical product during the trial, except
   a) if the loss arises from the fact that in the interest of the trial, other medical products or treatments that otherwise would be used for the mitigation of the given illness or condition, were withheld, or
   b) if the placebo having been given to the Trial Subject makes the refusal of the indemnification to be unreasonable;

8. claims directly or indirectly caused by or contributed to by or arising from ionising radiation or radioactive contamination by radioactivity from any nuclear fuel or any nuclear waste from the combustion of any nuclear fuel; or from the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof;

9. claims arising from Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type III (HTLV III) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named

10. claims arising from any condition directly or indirectly caused by or associated with Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) new variant Creutzfeldt-Jakob Disease (nvCJD) or Bovine Spongiform Encephalopathy (BSE)

11. claims made for Bodily Injury of whatsoever nature directly or indirectly caused by or contributed to or arising from
    a) asbestos, asbestos fibres, asbestos dust or any materials containing asbestos
    b) tobacco or any tobacco products (or ingredients thereof)
    c) lead

12. claims arising out of participation of pregnant women;

13. injuries resulting from genetic changes;

14. any claim or claims or legal proceeding instituted
    c) within the United States of America or Canada, or any other territories that come within the jurisdiction of the United States of America or Canada,
    d) to enforce a judgement obtained in any court of the United States of America or Canada, or any territories which come within the jurisdiction of the United States of America or Canada;

15. any liability losses that arise not from a legal rule but from a contract and exceeding the prevailing legal liability;

16. fines and penalties determined by courts or authorities;

17. any losses caused by or in consequence of:
    a) war, invasion, acts of foreign enemies, hostilities or warlike events (whether war be declared or not), civil war,
    b) permanent or temporary seizure, resulting from confiscation, military appropriation or requisition on the order of a legal authority,
    c) riot, strike, rebellion, separatist action, military or civil appraisal, insurrection, counterrevolution, revolution, military or usurped power, martial law or any other event or reason the declaration of which entails the introduction of martial law,

d) terrorist action committed by any organisation or any person or persons acting on behalf or in connection with such organisations.
(For the purpose of this exclusion terrorism shall mean any violent action with political goals, and any violent action aimed at putting the whole or a part of the population under terror.)

V. COVER UNEFFECTIVE BECAUSE OF THE INSURED'S (POLICYHOLDER'S) BREACH OF OBLIGATION

1. The Insurer shall be freed from obligation if the Insured (Policyholder) fails to comply with his/her reporting obligation outlined in Section VII and as a consequence substantial circumstances become concealed.

2. Should the obligation of reporting and reporting changes as determined in Section VII be violated, the Insurer shall be freed from the obligation to indemnify unless it is proved that the circumstance so concealed or not reported was known to the Insurer at the conclusion of the contract or it had no contribution to the occurrence of the insured event.

VI. RULES OF DATA DELIVERY AND PREMIUM PAYMENT

1. The premium for this insurance shall be determined as a function of the premium base, in proportion with the risk exposure.

2. The premium basis of this insurance shall be determined taking the following into consideration
   a) the limit of indemnity (limit of indemnification per event and in the aggregate),
   b) the investigational medicinal product,
   c) number of patients or non-patient volunteers involved,
   d) period of the trial and period regarding one patient or non-patient volunteer,
   e) the phase of the trial performed or sponsored by the Insured,
   f) the deductible chosen by the Insured (Policyholder) and
   g) the territorial scope.

3. The Insured shall provide the Insurer with all data necessary for the determination of the premium at the conclusion of the contract on the Schedule signed for and on behalf of the Insured, and forming an integral part of the insurance proposal.

3. The premium is due at the date determined by the parties. If not agreed otherwise the premium is due when the insurance contract is concluded.

4. In the event of non-payment of the insurance premium as due, the Insurer shall dispatch within thirty days from the due date a written request for payment to the Policyholder in default - indicating the potential legal consequences - with an additional thirty-day deadline from the date when the warning has been dispatched. In the event of non-payment within the additional period, the contract shall be terminated with retroactive effect to the original due date, except if the Insurance Company forthwith enforces its claim by judicial process.

VI. REPORTING AND CHANGE REPORTING OBLIGATION OF THE INSURED

1. At the conclusion of the contract the Insured shall be obliged to inform the Insurer on all circumstances that are relevant from the underwriting aspect and that were or should have been known to him. In order to comply with this obligation the Insured is to report any circumstances that he/she considers important even if not explicitly requested by the Insurer. The Insured is also obliged to report any changes in important circumstances to the Insurer.

2. The Parties agree that the Insured complies with the said reporting obligation during the contract period by reporting any changes to circumstances prevailing at the inception date within 8 working days to the Insurer in writing.

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If the Insured does not agree on the proposed amendments or does not respond within 15 days, the contract is terminated on the 30th day from the day when such proposal was made. The Insured should be informed on the above consequence simultaneously with the said proposal.

Should the Insurer not exercise its above mentioned right, the contract will remain in force with the original contents.

3. If the Insurer gains knowledge on circumstances that are relevant to the contract only after having concluded the contract or is being informed on changes of circumstances defined as important in the contract the Insurer may propose the amendment of the contract within 15 days, or - if according to the prevailing regulation the risk cannot be accepted – may cancel the contract with a 30 days' notice.

4. If the Insured does not agree on the proposed amendments or does not respond within 15 days, the contract is terminated on the 30th day from the day when such proposal was made. The Insured should be informed on the above consequence simultaneously with the said proposal.

5. Should the Insurer waive the above mentioned rights, the contract will remain in force with the original contents.

6. Any changes in the legal status of the Insured (e.g. separation, merger, cessation) should be reported to the Insurer within 8 working days.

VII. OBLIGATIONS OF THE INSURED FOLLOWING THE OCCURRENCE OF THE INSURED EVENT

1. Upon occurrence of an insured event or a claim made against him/her the Insured shall be obliged to report the same without delay in writing to the Insurer.

2. The claim report should include the following:
   a) description and date of the claim,
   b) name of the investigational medicinal product causing the injury,
   c) name of the medical institution and the investigator controlling the trial,
   d) seriousness of the injury (stated or estimated degree) - name and data of the persons injured and the degree of the injury,
   e) name, address and telephone number of the person designated by the Insured to participate in the loss adjustment.

3. The Insured shall be obliged to present the resolution of any public proceedings in respect of the insured event to the Insurer.

4. On the request of the Insured the Insurer shall represent the Insured in and out of court. In this case the costs of such representation shall be borne by the Insurer, however, subject to the provisions of section IX pt. 1.
   The Insured shall not admit any claim or make any compromise or pay any indemnification without the consent of the Insurer. Such commitment assumed or payment made by the Insured shall not be binding for the Insurer. Any condemnation made against the Insured in a civil procedure initiated by the claimant shall be binding for the Insurer only if the legal representation was overtaken by the Insurer or the Insurer participated in the process otherwise or abandoned the representation or participation in the preceedings.

VIII. SUM INSURED

1. The sum insured shown in the policy is the maximum amount payable by the Insurer in respect of any loss covered under this policy, including compensation, investigation, adjustment, appraisal and legal costs, process costs and default interests.

2. The total sum payable by the Insured in respect of one Trial Subject shall not exceed the sum insured per Trial Subject as determined in the policy.

3. The total sum payable by the Insured in respect of a Clinical Trial shall not exceed the sum insured determined for the total Clinical Trial in the policy.

X. RULES OF COMPENSATION AND AMOUNT OF INDEMNIFICATION

1. The Insurer shall indemnify for losses, net of deductible, up to the limit for any one event and in the aggregate (limit of indemnity) stated in the policy.

2. The compensation shall be paid as a lump sum indemnification.

3. The amount of compensation payable shall be appropriate to the nature, severity and persistence of the injury. It should be assessed with reference to the measurement and quantity of compensation that would have been awarded by the court of jurisdiction in the same period in a similar case.

4. Compensation shall not be denied or abated by reason of any contribution of a third party in causing the injury for which such third party can be made liable (joint liability). Upon settling the total claim, however, the Trial Subject's rights against such third party shall be subrogated to the Insurer.

5. The amount of the indemnification shall be paid by the Insurer to the Trial Subject within sixty days from the receipt of all data, deed, expertise and documentation proving the occurrence and the amount of the loss.
In connection with any claims against the Insured, the Insurer may at any time pay the Insured the amount equalling the Limit of Indemnity or any lesser amount for which such claims can be settled and thereupon the Insurer shall relinquish the control of such claims and be under no further liability in connection therewith except for the costs and expenses that the Insurer has already agreed to bear in respect of matters, prior to the date of such payment.

IX. DEDUCTIBLE

From the amount of compensation determined for each and every loss the Insured shall bear the amount of the deductible determined in the policy.

X. RECOVERY RIGHTS OF THE INSURER

1. The Insurer may request the reimbursement of the amount of compensation from the Insured (the Policyholder) if the loss was caused by the illegal, deliberate or grossly negligent action of the Insured.

2. For the purpose of this insurance gross negligence shall be if the Insured or his/her employee
   a) performed any activity bound to official licence without such licence
   b) performed his/her activity in absence of the personal and material conditions prescribed by the relevant legal rules or other requirements,
   c) caused the loss in drunken state or under the influence of stupefacient agents, or in consequence of such state, or
   d) the loss was the consequence of the material or repeated breach of the loss prevention, loss mitigation prescriptions or the professional regulations.

XI. LOSS PREVENTION AND LOSS MITIGATION OBLIGATION OF THE INSURED

1. The Insured shall be obliged to act with due diligence in order to prevent, eliminate or mitigate losses and fully observe the relevant prescriptions at all times.

2. The Insurer itself or its representative shall be entitled to supervise the execution of the loss prevention measures.

1. If the Insurer becomes aware of a serious breach of the provisions on loss prevention or a repeated failure to comply with them, it may, within fifteen days of becoming aware of such a breach, propose an amendment to the insurance contract or terminate the contract in writing with thirty days' notice.

2. If the Insured does not accept the proposed amendment or does not respond to it within fifteen days of its receipt, the insurance contract will be terminated on the thirtieth day after the date of notification of the proposed amendment.

XII. MISCELLANEOUS STIPULATIONS

1. Any claim arising from this insurance contract shall lapse after five years from its due date.

2. To facilitate the right to recourse of the Insurer the Insured is obliged to deliver all evidence and information necessary. Any disadvantages arising from the breach of this obligation shall be borne by the Insured.

3. The Policyholder or the Insured and the Insurer are obliged to make any declaration in writing (via letter or telefax).

4. The Insurer shall be entitled to inspect the risk exposure and the accuracy of the data submitted by the Insured any time on the spot.

5. Any debate out of this insurance contract, in particular in respect of its validity or interpretation of its terms and conditions, prescriptions, limits and/or exclusions shall be governed by the Law of Hungary.